No. 83-1925

in the

Supreme Court

of the

United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT
Appellants,

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellee.

APPELLEE'S BRIEF ON THE MERITS

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QUESTIONS PRESENTED

A. Where the federal legislation and attendant regulation in a given field is pervasive, what is the proper test to be applied in determining whether local legislation in the same field is pre-empted?

B. Does application of the appropriate test for pre-emption mandate a holding that the subject Hillsborough County ordinances regulating the plasmapheresis procedure are pre-empted by federal regulation of the plasmapheresis procedure under the Public Health Service Act?

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OPINIONS AND JUDGMENTS BELOW

The opinion (JA 40-46)[1] and final judgment (JA 47) of the United States District Court for the Middle

[1]References to the Joint Appendix are indicated by (JA), the Jurisdictional Statement Appendix by (JSA), and the Transcript by (TR).

District of Florida, William J. Castagna, J., are not reported. The opinion (JA 48-59) of the United States Court of Appeals for the Eleventh Circuit is reported at 722 F.2d 1526. The final judgment (JA 60) is not reported.

JURISDICTION

The judgment of the Court of Appeals was entered on January 16, 1984 (JSA 21). A petition for rehearing by panel was denied on February 23, 1984 (JSA 22-26) and a notice of appeal was filed on April 20, 1984 (JSA 27). This Court noted probable jurisdiction on January 14, 1985. The jurisdiction of this Court rests upon 28 U.S.C. §1254(2).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding. United States Constitution, Article VI, clause 2.

2. Public Health Service Act, Sections 351 & 361, 42 U.S.C. §§262 & 264.

3. Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321, *et. seq.*

4. 21 C.F.R. §600.3-680.26 (1983).

5. Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder (JA 21-34).

STATEMENT OF THE CASE

On November 26, 1980, Appellant, HILLSBOROUGH COUNTY, FLORIDA ("County"), adopted Ordinances 80-11 and 80-12 (JA 21-31), purporting to regulate plasmapheresis establishments and the eligibility of donors of blood plasma.[2] Ordinance 80-11 (JA 21-23) imposed a license tax on blood plasma centers, and required licensees, among other things, to permit inspection of blood plasma centers by Appellant HILLSBOROUGH COUNTY HEALTH DEPARTMENT ("Department"). Ordinance 80-11, in addition, required blood plasma centers located within Hillsborough County to provide continuously updated information to the Department regarding their ownership, employees, equipment and facilities.

Ordinance 80-12 (JA 24-31), and the rules and regulations promulgated thereunder (JA 32-34), required that a blood plasma donor, prior to donating plasma, undergo a medical examination and obtain a certificate of good health, and to obtain from the Department an identification card, which identification card would have

[2]Plasmapheresis is a process whereby, during a single procedure, blood is removed from a human donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor (JA 50; 722 F.2d at 1527-1528; *see also*, 21 C.F.R. §606.3(e)).

permitted the potential donor to undergo plasmapheresis for a period of six months only, and only at a single specified plasma center within Hillsborough County. Ordinance 80-12 also required licensee plasma centers to submit to the Department, on a daily basis, and as to each procedure performed, detailed information regarding the donor, reports of testing, and results of the procedure. Ordinance 80-12 also required licensee plasma centers to pay to the Department a fee of $1.00 for each procedure performed.

Appellee, AUTOMATED MEDICAL LABORATORIES, INC. ("AML"), a Florida corporation which, through a wholly owned subsidiary corporation known as Tampa Plasma Center, operates a blood plasma center in Tampa, Hillsborough County, Florida, filed a civil action against the County and the Department in the United States District Court for the Middle District of Florida, challenging the constitutionality of the Ordinances (JA 5-34). AML's complaint challenged the County regulatory scheme on the grounds that it was pre-empted by regulations of the United States Food and Drug Administration ("FDA") (21 C.F.R. Subchapter F-Biologics), that it imposed an undue burden on interstate commerce, that it denied AML its right to equal protection of the law, and for other reasons.

After a non-jury trial, the United States District Court for the Middle District of Florida entered its opinion (JA 40-46) and final judgment (JA 47), on November 1, 1982, holding §7 of Ordinance 80-12 and §4 of the rules and regulations (dealing with required breathalyzer tests) unconstitutional, as impermissibly burdening interstate commerce, and upholding the remainder of the County regulatory scheme.

AML appealed to the United States Court of Appeals for the Eleventh Circuit, and the County cross-appealed with respect to the portions of the Ordinances invalidated by the District Court.

The Eleventh Circuit held that Ordinances 80-11 and 80-12 were invalid, because the County regulatory scheme was wholly pre-empted by federal regulation of the area, under the tests enunciated in *Pennsylvania v. Nelson*, 350 U.S. 497, 76 S.Ct. 477 (1956) (JA 48-59; 722 F.2d 1526 (1984)). Accordingly, the Eleventh Circuit did not decide the other questions raised on the appeal.

Hillsborough County petitioned for rehearing by panel (JSA 22-25). In its petition, the County explicated its view that the Eleventh Circuit had erred in holding that federal law pre-empted its Ordinances, had ignored record evidence and had misapplied the law. The Eleventh Circuit denied the petition for rehearing (JSA 26).

SUMMARY OF ARGUMENT

Pursuant to the Supremacy Clause of the United States Constitution, the laws of the United States are "the supreme Law of the Land." Accordingly, local legislation that interferes with, or is contrary to, federal law is invalid under the doctrine of federal pre-emption.

In interpreting and applying the Supremacy Clause, and in establishing and defining the doctrine of federal pre-emption, this Court consistently has held that where Congress intends, either expressly or impliedly, that a federal regulatory system covering an area of permissible federal regulation is the exclusive regulatory system, local legislation in that area is pre-empted.

It is equally well-settled that, when promulgated with appropriate legislative authority, federal regulations have pre-emptive effect equal to that of federal statutes.

The first step, then, in a proper pre-emption analysis is an examination of the statutory and regulatory framework. In the case at bar, the system of federal regulation of the plasmapheresis industry is grounded upon the Public Health Service Act, 42 U.S.C. §262, *et seq.* (and, to a much lesser degree, upon the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321, *et seq.*).[3]

The relevant portions of the Public Health Service Act provide that no person shall sell any blood component or derivative (including blood plasma collected by plasmapheresis) unless the product was propagated or manufactured at an establishment holding a valid license from the Food and Drug Administration ("FDA"). Licenses for plasmapheresis establishments are, in turn, granted pursuant to extensive FDA regulations promulgated to ensure the safety and purity of blood components, to ensure the safety of the (paid) donors of plasma who undergo the plasmapheresis procedure, and to ensure the continued adequate supply of plasma, collected by the plasmapheresis procedure and subsequently manufactured into vitally important pharmaceutical products.

Acting pursuant to the statutory authority of Section 361 of the Public Health Service Act, the FDA has

[3]The statutory framework for the federal regulation of the plasmapheresis industry is described at pages 1-4 of the Brief for the United States, as *Amicus Curiae*. AML finds that description to be accurate.

promulgated comprehensive regulations,[4] found by the United States Court of Appeals for the Eleventh Circuit in this case to be pervasive, to be broad in scope and to "cover virtually every phase of the plasmapheresis process" (JA 56; 722 F.2d at 1531). There is no dispute among the parties as to the comprehensiveness of the regulations.

In its analysis of the doctrine of federal pre-emption as applied to the facts of the case at bar, the Eleventh Circuit carefully considered the correct, well-settled and recently restated principles of pre-emption analysis. The Eleventh Circuit concluded that, while the statutes and regulations involved do not expressly pre-empt local legislation, the federal system of regulation has, by implication, pre-empted local legislation.

More specifically, the Eleventh Circuit carefully applied the tests for determining the issue of implied pre-emption, as articulated in *Pennsylvania v. Nelson*, 350 U.S. 497, 76 S.Ct. 477 (1956), and concluded that (i) the federal regulations are comprehensive and fill the entire field of regulation, (ii) the federal law concerns a field of dominant federal interest and (iii) enforcement of the County legislation would present a serious danger of conflict with the administration of the federal system. (JA 55-59; 722 F.2d at 1531-1533). Accordingly, the Eleventh Circuit held the Hillsborough County Ordinances to be invalid, because local regulation in the field had been pre-empted.

[4]The FDA regulations are found at 21 C.F.R. Parts 600, 601, 606, 607, 610 and 640, Subpart G.

The County's brief indicates substantial agreement with AML on the correct principles of pre-emption analysis applicable to the case at bar. However, without advancing persuasive reasons in support of their position, the County argues that the Eleventh Circuit misapplied the principles of pre-emption analysis.

Amici curiae supporting the County argue that the Eleventh Circuit applied incorrect principles of pre-emption analysis in finding that the federal regulatory system pre-empts local legislation. More specifically, the National Association of Counties, *et al.*, with misplaced reliance upon *Fidelity Federal Savings & Loan Ass'n. v. de la Cuesta*, 458 U.S. 141, 102 S.Ct. 3014 (1982) and *Capital Cities Cable, Inc. v. Crisp*, ____ U.S. ____, 104 S.Ct. 2694 (1984), argue that, in the absence of explicit statutory language of pre-emption, a finding of express agency intent to pre-empt is required before agency regulations pre-empt state law. The United States argues that this Court cannot find implied pre-emption where the agency initially indicated a lack of intent to pre-empt local legislation.

The authorities relied upon by the National Association of Counties, *et al.* and by the United States do not, upon proper analysis, stand for the propositions being urged by the *amici curiae* supporting the County. Proper determination of this case does not require a departure from established principles of pre-emption analysis.

For the reasons stated above, and fully discussed in Point II below, the Eleventh Circuit applied the proper legal standard in concluding that the Hillsborough County ordinances at issue are pre-empted by the federal

regulatory system authorized by the Public Health Service Act and effectuated by regulations of the FDA.

For the reasons summarized below and fully discussed in Part III, application of well-settled principles of pre-emption analysis mandates a holding that the conclusion reached by the Eleventh Circuit, that the challenged ordinances are wholly pre-empted and cannot stand, was correct.

As recently as June 1984, this Court restated the three possible bases for a determination that local legislation has been pre-empted by federal law: (1) in enacting a federal statute, Congress may explicitly state that it intends to pre-empt state law (express pre-emption); (2) in the absence of language expressly pre-empting state legislation,[5] Congress may, nevertheless, indicate its intent to occupy an entire field of regulation, thereby precluding the states from regulating in that area (implied pre-emption); and (3) even in the absence of express or implied congressional intent to displace state law in its entirety, state law may be pre-empted to the extent that the state law actually conflicts with federal law, either when compliance with both state and federal law is impossible, or when the state law presents an obstacle to the purposes and objectives of Congress (obstacle). *Capital Cities Cable, Inc. v. Crisp, supra*, ____ U.S. at ____, 104 S.Ct. at 2700-01.

The principles enunciated in *Capital Cities* are consistent with, and follow, an established line of decisions

[5]Local ordinances are treated as are state statutes for these purposes. *City of New Orleans v. Dukes*, 427 U.S. 297, 96 S.Ct. 2513 (1976).

of this Court. *See, e.g., Michigan Canners & Freezers Ass'n. v. Agricultural Marketing and Bargaining Board.* ___ U.S. ___, 104 S.Ct. 2518 (1984); *Jones v. Rath Packing Co.*, 430 U.S. 519, 97 S.Ct. 1305 (1977); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 67 S.Ct. 1146 (1947); *Bethlehem Steel Co. v. New York State Labor Relations Bd.*, 330 U.S. 767, 67 S.Ct. 1026 (1947). Federal regulations can have the same pre-emptive effect as do federal statutes. *Fidelity Federal v. de la Cuesta, supra,* ___ U.S. at ___, 102 S.Ct. at 3022; *Capital Cities Cable, Inc. v. Crisp,* ___ U.S. at ___, 104 S.Ct. at 2700.

The case at bar is not an instance in which Congress or the FDA has explicitly stated an intent to pre-empt. Therefore, the first possible basis for a finding of pre-emption is inapplicable.

In the absence of express pre-emption, an analysis of whether Congress or the appropriate federal agency has impliedly pre-empted local law is required. There are two instances in which implied pre-emption will be found: (i) where the federal system of regulation is so pervasive as to fill the field of regulation, or (ii) where the federal interest in the area regulated is dominant over any local interest.

The first test for implicit federal pre-emption is met in the case at bar because the federal system for regulation of blood and blood products, established pursuant to Section 351 of the Public Health Service Act ("the Act"), is so pervasive as to leave no room for state regulation of the plasmapheresis industry. Section 351 of the Act requires federal licensing of each

establishment producing a biological product, federal licensing of each product to ensure safety, purity and potency, and federal standards for packing and labeling of the product. The FDA regulations implementing the Act contain a section dealing specifically with "Source Plasma (Human)," as well as more general sections which apply to the plasmapheresis procedure itself. The federal regulatory system is so comprehensive and extensive as to compel the conclusion that Congress and the FDA have left no room for state regulation in the field of plasmapheresis.

The second test for implicit pre-emption is met, in that at least in the areas of product purity, donor safety and adequate plasma supply, the federal interest in the plasmapheresis field is so dominant that local legislation is precluded. Section 351 of the Act prohibits the sale or transportation of any blood or blood product which has not been propagated or manufactured and prepared at a federally licensed establishment. Section 361 of the Act (42 U.S.C. §264) authorizes the FDA to promulgate such regulations as are necessary to prevent the introduction, transmission, or spread of blood related communicable disease from one state to another. This necessarily requires the FDA to exercise its authority to regulate a potential disease-causing substance from the source of its collection through its subsequent processing (or manufacture) and shipment. The FDA, in promulgating the regulations concerning biological products, established a comprehensive National Blood Policy and employed the full regulatory authorities vested in the federal government to assure uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis. The statutory

language and the regulatory framework indicate that Congress intended uniform national standards to promote product purity, donor safety and an adequate plasma supply.

The County concedes that the concern of its local legislation is the source of the blood product, that is, the donor. The concern for donor safety, then, is shared by the County and the FDA. However, given the federal congressional and regulatory intent to establish a uniform, comprehensive national program in the area, and the FDA's duty to issue all regulations it deems necessary to effect that goal, it is apparent that Congress intended uniform national standards that would foreclose the imposition of different or more stringent local requirements.

Because federal regulation of plasma and plasmapheresis is so pervasive, and because the federal interest in regulating the field is so dominant as to preclude enforcement of local laws on the subject, the federal regulatory system implicitly pre-empts enforcement of the County's ordinances.

Even if Congress and the FDA have not implicitly pre-empted state regulation of the plasmapheresis industry, enforcement of the challenged local legislation would result in both an irreconcilable conflict with federal regulations and a substantial obstacle to the full attainment of congressional objects and purposes in regulating blood and blood products. The County ordinances, including a restrictive donor registration requirement, a pre-registration hepatitis test, a pre-donation breath analysis for alcohol content and detailed recordkeeping and reporting requirements, impose

burdensome and expensive requirements in addition to the extensive federal regulatory system. If enforced, the County's legislation would conflict with federal regulation authorizing the collection of hepatitis plasma for vaccine manufacture and would frustrate the congressional goals of ensuring a safe and adequate blood supply and ensuring a continued supply of healthy donors.

ARGUMENT

POINT I

THE DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT SHOULD BE SUMMARILY AFFIRMED.

AML filed its Motion to Affirm with this Court on June 27, 1984. For the reasons stated therein, this Court should now, AML respectfully submits, summarily affirm the decision of the United States Court of Appeals for the Eleventh Circuit.

The controlling issues have now been fully briefed in this Court, and, under the current and well-settled state of the law of pre-emption, it is abundantly clear, for the reasons fully discussed in Point II below, that the Eleventh Circuit applied the appropriate legal principles in determining that Hillsborough County Ordinances 80-11 and 80-12 are pre-empted by federal law. For the reasons fully discussed in Points III and IV below, the Eleventh Circuit correctly determined, under the tests set forth in *Pennsylvania v. Nelson*, 350 U.S. 497, 76 S.Ct. 477 (1956), that the Hillsborough

County ordinances were pre-empted by the federal regulatory system.

POINT II

THE COURT OF APPEALS APPLIED THE PROPER LEGAL STANDARD IN DETERMINING THAT THE CHALLENGED LOCAL LEGISLATION WAS PRE-EMPTED.

A. The basic principles of pre-emption analysis are well settled and free of doubt.

It is axiomatic that the doctrine of federal pre-emption is grounded upon the Supremacy Clause of the United States Constitution, Article VI, clause 2:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land; . . .

Since as early as 1824, the Supremacy Clause, as the foundation for the doctrine of federal pre-emption, has been interpreted and applied to invalidate local laws that "interfere with, or are contrary to" federal law. *Gibbons v. Ogden*, 9 Wheat. 1, 211 (1824).

It is also firmly established that "(f)ederal regulations have no less pre-emptive effect than federal statutes." *Fidelity Federal v. de la Cuesta, supra*, 458 U.S. at 153-54, 102 S.Ct. at 3022; *Capital Cities Cable, Inc. v. Crisp*, ____ U.S. at ____, 104 S.Ct. at 2700:

> . . . Under the Supremacy Clause, U.S. Const., Art. VI, cl. 2, the enforcement of a state regulation may be pre-empted by federal law in several circumstances: first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law, *Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977); second, when it is clear, despite the absence of explicit pre-emptive language, that Congress has intended by legislating comprehensively, to occupy an entire field of regulation and has thereby "left no room for the States to supplement" federal law, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947); and, finally, when compliance with both state and federal law is impossible, *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143, 83 S.Ct. 1210, 1217-1218, 10 L.Ed.2d 248 (1963), or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 404, 85 L.Ed 581 (1941). See also *Michigan Canners & Freezers Assn. v. Agricultural Marketing and Bargaining Board*, ____ U.S. ____, ____, 104 S.Ct. 2518, ____, 80 L.Ed.2d ____(1984).

And, as we made clear in *Fidelity Federal Savings and Loan Assn. v. De La Cuesta*, 458 U.S. 141, 102 S.Ct. 3014, 78 L.Ed.2d 664 (1982).

> "Federal regulations have no less pre-emptive effect than federal statutes
> . . .

* * *

The cases cited above flow consistently in a long stream of cases expressing these now familiar principles. See, e g.: *Bethlehem Steel Co. v. Allegheny Ludlum Steel Corp.*, 330 U.S. 767, 67 S.Ct. 1026, (1947); *Rice v. Santa Fe Corporation.*, 331 U.S. 218, 67 S.Ct. 1146 (1947); *Jones v. Rath Packing Co.*, 430 U.S. 519, 97 S.Ct. 1305 (1977); *Michigan Canners, supra*, ___ U.S. ___, 104 S.Ct. 2518 (1984).

B. Contrary to the position advanced by the National Association of Counties, a finding of express agency intent to pre-empt is not a prerequisite to a holding that the federal regulatory system governing the plasmapheresis industry pre-empts the challenged Hillsborough County ordinances.

Although the principles set forth above would appear to be certain, the primary substantive disagreements among the parties (and *amici curiae*) in this case arise at this point in the pre-emption analysis.

In the case at bar, the Eleventh Circuit found that the language of the statutes upon which the comprehensive FDA regulatory system is based, the Public Health Service Act and the Federal Food, Drug and Cosmetic Act, does not support a finding of express congressional intent to pre-empt (JA 54-55; 722 F.2d at 1530). From that finding, coupled with an unsound analysis of *Fidelity Federal v. de la Cuesta*, the National Association of Counties asks this Court to adopt an entirely novel approach to pre-emption analysis and to depart from the well settled rules of law expressed above. The National Association of Counties advances the position

that, in the absence of express congressional intent to pre-empt, a finding of pre-emption by agency regulation is proper only if the agency has expressly stated its intent to pre-empt local legislation.[7]

It hardly merits stating that, in accordance with modern day concepts of federalism, Congress frequently provides the statutory basis for federal control over a given field, and delegates to an agency the task of promulgating and enforcing the detailed regulatory system. *Bethlehem Steel Co. v. New York State Labor Relations Bd.*, 330 U.S. 767, 67 S.Ct. 1026 (1947). This, of course, is the context of the case at bar, namely, a congressional enactment stating essential federal principles and policy, with appropriate authority granted to the proper agency to enact controlling regulations. This gives rise to the issue of whether the system of federal regulation has pre-empted local legislation in the field.

In such circumstances, this Court has repeatedly found local regulation to be pre-empted, even without a finding of express agency intent to pre-empt. *Capital Cities Cable, Inc. v. Crisp* ___ U.S. ___, 104 S.Ct. 2694 (1984) (Federal Communications Commission regulations promulgated under Communications Act of 1934); *Jones v. Rath Packing Co.*, 430 U.S. 519, 97 S.Ct. 1305 (1977) (Secretary of Agriculture regulations promulgated under Federal Meat Inspection Act); *Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 98 S.Ct. 988 (1978) (Department of Transportation regulations promulgated under Ports and Waterways Safety Act of 1972); *Franklin National*

[7]Brief of the National Association of Counties, *et. al.*, as *Amici Curiae*, p. 16.

Bank v. New York, 347 U.S. 373, 74 S.Ct. 550 (1954) (Federal Reserve Board Regulations promulgated under Federal Reserve Act).

In short, the National Association of Counties' position represents a radical departure from the established precedent of this Court.

In addition, *Fidelity Federal v. de la Cuesta* simply does not stand for the proposition advanced—that a finding of pre-emption "requires a clear expression of administrative intent to preempt all state efforts, including non-conflicting laws, to regulate the same subject."[8] In fact, *Fidelity Federal v. de la Cuesta* restates the classic principles of pre-emption analysis and explicitly recognizes that "federal regulations have no less pre-emptive effect than federal statutes." ____ U.S. at ____, 102 S.Ct. at 3022. The issue in *Fidelity Federal v. de la Cuesta* was whether the agency expressing the intent to pre-empt did so with proper congressional authority. *Fidelity Federal v. de la Cuesta* cannot be construed to stand for the proposition asserted by the National Association of Counties.

C. The position advanced by the United States is contrary to controlling precedent.

The position advanced by the United States appears to differ from the position of AML in only one, but one quite substantial, respect. The United States acknowledges, as indeed it must, that the subject FDA regulations are "comprehensive" and that:

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[8]Brief of National Association of Counties, *et. al.*, as *Amici Curiae*, p. 16.

> [t]he purpose of the FDA regulations is to establish nationwide standards necessary to provide an adequate supply of safe, pure and potent blood, blood components, and blood products, *as well, as to protect the health of blood donors.*[9]

The United States argues, however, that because a comment made at the time the initial regulations were proposed indicates a lack of intent to pre-empt, this Court cannot find implied pre-emption despite the facts that the regulations are comprehensive in scope, and concern an area in which the federal interest is dominant, and the County ordinances have the same goal as the federal regulations. However, later comments by the Commissioner indicate that the agency soon thereafter felt constrained to take steps to ensure that the plasmaphleresis regulations were uniform, comprehensive and applicable nationwide. *See e.g.*, 39 *Fed. Reg.* 18614-15 (1974). The present scope of the federal regulations should be considered by the Court in determining if a finding of pre-emption is now appropriate. *Edgar v. MITE Corp.*, 457 U.S. 624, 633, 102 S.Ct. 2629, 2636 (1982).

AML's position, that a federal regulatory system impliedly pre-empts the entire field of regulation when (i) the federal law fills the field by its pervasiveness or (ii) the federal law regulates a field of dominant federal interest, is fully supported by the cases cited in Point II, B above. The fact that the United States concedes the pervasiveness of the FDA plasmapheresis regulations,

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[9]Brief for the United States, as *Amicus Curiae*, p. 7 (emphasis supplied).

and the importance of the national interest thusly served, adds substantial weight to AML's position that the Eleventh Circuit's holding of implicit federal pre-emption of the field of plasmapheresis was sound and should be affirmed.

Of particular importance is the fact that the United States admits that the federal regulations have as one of their purposes the same purpose as the County ordinances, namely the protection of the health of the donors. The law is well settled that when local legislation has the same purpose as a comprehensive federal regulatory system, local legislation in any area of that field is pre-empted. *Ray v. Atlantic Richfield Company*, 435 U.S. 151, 98 S.Ct. 988 (1978).

The facts in *Ray* are strikingly similar to those in the case at bar. Pursuant to statutory authority, the Secretary of Transportation was to promulgate "comprehensive minimum standards" for the design and structure of certain cargo carrying vessels. After promulgating such standards, the Secretary was to then provide for inspection for compliance with the minimum requirements, and to issue certificates if the federal standards were satisfied. The State of Washington attempted to impose additional and more stringent requirements to accomplish the same goal as the Secretary's, namely vessel safety. Applying well established principles of pre-emption analysis, this Court held that "[t]he Supremacy Clause dictates that the federal judgment that a vessel is safe to navigate United States waters prevails over the contrary state judgment." *Ray v. Atlantic Richfield Co.*, 435 U.S. at 165, 98 S.Ct. at 998. This Court went on to find that to allow the state to impose additional and more stringent

requirements on vessel design and safety would frustrate the congressional purpose of establishing uniform national standards, which if met, allow a vessel to operate. Thus, because Hillsborough County has admittedly "enacted a regulatory scheme governing [the area covered by the FDA regulations]",[10] and that scheme imposes additional and more stringent requirements than those imposed by federal law, the local legislation is pre-empted entirely.

D. The Court of Appeals applied the proper legal standard in determining that the Hillsborough County ordinances are pre-empted.

Thus, for the reasons stated above, the correct legal standard was utilized by the Eleventh Circuit in its analysis of this case. And, as will be demonstrated in Point III below, application of those well established pre-emption standards compels the conclusion that the challenged County ordinances are pre-empted.

POINT III

PROPER APPLICATION OF WELL-SETTLED PRINCIPLES OF IMPLIED PRE-EMPTION ANALYSIS MANDATES THE CONCLUSION THAT THE CHALLENGED ORDINANCES ARE WHOLLY PRE-EMPTED AND CANNOT STAND.

The Eleventh Circuit, in determining that the federal system for regulating blood plasma and plasmapheresis

[10]Brief for the United States, as *Amicus Curiae*, p. 7.

implicitly pre-empted the County's regulation of the area, applied the tests set forth in *Pennsylvania v. Nelson*, 350 U.S. 497, 76 S.Ct. 477 (1956), the identical tests recently restated by this Court in *Fidelity Federal v. de la Cuesta, supra*, 458 U.S. 141, ____, 102 S.Ct. 3014, 3022 (1982): (i) whether the federal scheme is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it, or (ii) whether the federal system of regulation controls a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject.

The Eleventh Circuit was eminently correct in holding that, based upon the criteria set forth in *Pennsylvania v. Nelson*, as restated in *Fidelity Federal v. de la Cuesta*, the County regulation of plasma and plasmapheresis is implicitly pre-empted by the federal system regulating the area.

A. Federal regulation of blood plasma and plasmapheresis is so pervasive as to leave no room for local regulation of the area.

The first test for determining the existence of implied federal pre-emption is whether federal regulation of the area is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it. *Pennsylvania v. Nelson*, 350 U.S. at 502, 76 S.Ct. at 480. In the case at bar, the federal system for regulation of plasmapheresis is so extensive as to require such an inference.

As the Eleventh Circuit noted, Section 351 of the Public Health Service Act (the "Act") requires federal licensing of each establishment producing a biological product, federal licensing of each such product to ensure safety, purity and potency, and federal standards for packaging and labeling of the product. 42 U.S.C. §262 (1982). Section 351 and Section 361 (42 U.S.C. §264) of the Act delegate to the FDA the authority to promulgate the rules and regulations required to implement the Act. (JA 56; 722 F.2d at 1531).

The regulations implementing the Act include a section dealing specifically with "Source Plasma (Human)," which is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. 21 C.F.R. §640.60-640.76 (1983).[11] Other portions of the regulations promulgated pursuant to the Act also apply to, and regulate, virtually every aspect of the plasmapheresis industry.[12] *Id.*

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[11]The regulations prescribe rules as to consent of a prospective donor, medical supervision of the procedure, suitability of donors, method of collection, requirements of the plasmapheresis procedure, immunization of donors, testing for hepatitis, processing of the blood, pooling, inspection, labeling, manufacturing responsibility, records, reporting of fatal donor reactions, modification of source plasma, alternate procedures, and products stored or shipped at unacceptable temperatures (JA 56, fn.4; 722 F.2d at 1531, fn.4).

[12]The subjects included within the remaining regulations are establishment standards and inspections, 21 C.F.R. §§600.3-22 (1983); licensing, 21 C.F.R. §§601.1-601.33 (1983); good manufacturing practices for blood and blood components, 21 C.F.R. §§606.3-606.170 (1983) (with specific sections relating to personnel, facilities, equipment, supplies and reagents, standard operating procedures, finished product and laboratory controls, labeling, records, and reports);

Clearly, as found by the Eleventh Circuit, the federal regulations are broad in their scope and cover virtually every phase of the plasmapheresis process. The federal regulatory system is so comprehensive and extensive that the only reasonable inference that may be drawn is that Congress and the FDA have left no room for local regulation in the plasmapheresis field.

B. At least in the areas of product purity, donor safety and adequate plasma supply, the federal interest is so dominant that local legislation is precluded.

The second basis for a finding of implicit federal pre-emption is a finding that the federal regulatory system covers a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject. *Pennsylvania v. Nelson*, 350 U.S. at 504, 76 S.Ct. at 481. In the case at bar, the federal interest in ensuring a safe and adequate supply of blood and blood components, and in ensuring the safety of the donors, as demonstrated by congressional act and federal agency regulation, dominates over any local interest in those areas.

Again, as found by the Eleventh Circuit, Congress and the FDA have maintained extensive and comprehensive control over the nation's blood collection system since 1946. 38 *Fed. Reg.* 2966 (1973). The collection

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(Footnote 12 Continued)

establishment registration and product listing, 21 C.F.R. §§607.3-607.65 (1983); general biological products standards, 21 C.F.R. §610.65 (1983) (including standards of potency, hepatitis requirements, dating periods, and labeling standards) (JA 56, fn.5; 722 F.2d at 1531, fn.5).

of blood is an area of national concern, for "[h]uman blood is a priceless resource." 39 *Fed. Reg.* 18614 (1974) (JA 57; 722 F.2d at 1531).

Section 351 of the Act prohibits the sale or transportation of any blood or blood product that has not been propagated (or manufactured) and prepared at a federally licensed establishment. Pursuant to Section 361 of the Act (42 U.S.C. §264) and under the authority delegated under 21 C.F.R. §20.21, the FDA is authorized to promulgate such regulations as are necessary to prevent the introduction, transmission, or spread of blood related communicable disease from one state to another, necessarily requiring the FDA to exercise its authority to regulate a potential disease-causing substance from the source of its collection through its subsequent processing (or manufacture) and shipment. 39 *Fed. Reg.* 18614 (1974).[13]

In promulgating regulations concerning good manufacturing practices for blood and blood components, the Commissioner of Food and Drugs stated that:

> The promulgation of standards for these biological drugs is part of an existing effort to increase the quality of blood related health care in this country. Pursuant to the findings of a special Task Force in Blood Banking, the Secretary of Health, Education, and Welfare has established a *comprehensive National Blood*

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[13]In 1974, the FDA expressly acknowledged that the inspection or licensing provisions enacted by approximately ten states were inadequate to protect against the spread of hepatitis in blood products. 39 *Fed. Reg.* 18614-18615 (1974).

> *Policy*. One of the fundamental methods prescribed by the Secretary to implement the policy is to "employ the full regulatory authorities now vested in the Federal Government * * * for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."

39 *Fed. Reg.* 18614 (1974) (emphasis supplied).

The FDA, therefore, has developed a "comprehensive regulatory program" concerning blood and blood products.[14] The FDA's express purposes in promulgating regulations to implement that program are to ensure a safe and adequate supply of blood and blood products and to ensure a continuous and healthy donor population. 41 *Fed. Reg.* 10762-10763 (1976); 39 *Fed. Reg.* 26161-26162 (1974); 39 *Fed. Reg.* 18615 (1974).

The United States, in its Brief, acknowledges that, insofar as those goals are concerned, the federal interest so dominates as to foreclose local legislation on the subject.

> The federal government has required vendors nationwide to be subject to the same minimum product and donor safety standards to further the two-fold interest in ensuring that the national supply of safe, pure, and potent blood plasma remains adequate to meet the nation's health care needs and in protecting the health of donors for their own sake and to provide a healthy donor population. To that extent, the federal interest in plasmapheresis is dominant and the states are foreclosed from promoting a contrary policy.[15]

[14]*See, supra*, fn. 12 and 13.

The County attempts to create a distinction between the purposes of the federal regulation and those of the local ordinances, asserting that the purpose of the local legislation is to protect the health of the donor of the plasma, while the purpose of the federal regulations is to ensure the purity and adequacy of supply of the product (Appellant's Brief on the Merits, p. 10). However, as demonstrated above, the distinction sought to be made by the County is illusory.

The federal regulatory system aims at ensuring an adequate supply of blood and blood products, maintaining product safety and protecting and maintaining a sufficient supply of healthy donors. Congress, insofar as those aims are concerned, has entrusted to the FDA the duty of promulgating all regulations necessary to meet those ends. Section 351 of the Act, and the attendant regulatory framework, clearly demonstrates that Congress intended uniform national standards in the areas of product safety and supply and donor protection that would foreclose the imposition of more stringent local requirements in those areas. *Ray v. Atlantic Richfield Co.*, 435 U.S. at 164, 98 S.Ct. at 998 (1978).

AML does not, of course, assert that, by reason of the federal regulatory system, it is free to ignore local

[15]Brief of the United States, as *Amicus Curiae*, p. 23.

regulation in areas not covered by the federal regulations, such as local occupational licensing or general health and safety requirements. See, e.g., *Huron Portland Cement Co. v. City of Detroit, Michigan*, 362 U.S. 440, 80 S.Ct. 813 (1960) (federal approval and licensing of vessels to ensure seagoing safety did not preclude enforcement of municipal smoke abatement ordinance); *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n.*, 461 U.S. 190, 103 S.Ct. 1713 (1983) (federal regulation of radiological safety in construction and operation of nuclear power plants did not preclude state regulation concerning need, reliability and cost). However, the local ordinances at issue in this case relate only to the precise areas encompassed by the federal regulations.

The County attempts to regulate in areas which have been identified as being of dominant federal concern. The County is precluded from imposing requirements which are different from, or more stringent than those dictated to promote the comprehensive national program in that area, and, thus the County ordinances, are impliedly pre-empted by the federal regulatory system.

POINT IV

BECAUSE ENFORCEMENT OF THE CHALLENGED LOCAL LEGISLATION WOULD RESULT IN BOTH AN IRRECONCILABLE CONFLICT WITH FEDERAL REGULATIONS AND A SUBSTANTIAL OBSTACLE TO FULL ATTAINMENT OF CONGRESSIONALLY MANDATED OBJECTS AND PURPOSES, THE LOCAL LEGISLATION IS PRE-EMPTED.

Even if the pervasiveness of the federal regulations (Point III, A) and the dominance of the federal interest in the subject matter of those regulations (Point III, B) were not enough to imply pre-emption of the County ordinances, enforcement of the ordinances would conflict with the federal regulations and stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in establishing a national policy with regard to blood and blood products. These circumstances alone compel a finding that the challenged legislation is pre-empted. *Capital Cities Cable, Inc. v. Crisp*, ____ U.S. at ____, 104 S.Ct. at 2700; *Michigan Canners, supra*, ____ U.S. at ____, 104 S.Ct. at 2523; *Fidelity Federal v. de la Cuesta, supra*, ____ U.S. at ____, 102 S.Ct. at 3022.

The United States recognizes a conflict between the County ordinances and the federal regulations. If the County ordinances were to be enforced, plasmapheresis centers in Hillsborough County would be prevented from collecting plasma necessary for

production of hepatitis vaccine.[16] This conflict alone mandates a holding of pre-emption.

More substantially, enforcement of the County ordinances would stand as a serious obstacle to the expressly stated federal goal to "insure there is a continued healthy donor population to serve as a source of plasma." 37 *Fed. Reg.* 17420 (1972). In fact, AML's evidence at trial demonstrated that enforcement of the County ordinances would render the continued existence of AML's plasma center in Tampa economically impossible by substantially increasing costs of plasma production, while, at the same time, substantially reducing the donor population.

In particular, enforcement of the County ordinances would have such a negative effect upon local plasma centers that the donor population would be significantly reduced, resulting, obviously, in a diminished supply of available plasma. The evidence at trial indicated that enforcement of the County ordinances would result in an increase in direct costs of plasma production by $1.50 per litre, and a total increase in production costs (including both direct and indirect costs) of $7.00 per litre of plasma, an increase of approximately 15% in the total cost of production (TR 49-52; AML Trial Exhibit 19). In fact, prior experiences with a virtually identical set of ordinances indicate that the number of plasma centers would be reduced, in addition to reducing the donor population. Similar ordinances have been in effect in Miami, and since their enactment the number of plasma centers has been reduced from eleven until only two currently remain (AML Trial Exhibits 4 and 5).

[16]Brief of United States, as *Amicus Curiae*, pp. 29-30.

Donor population would be reduced by the complete elimination of what is known as the "casual donor." A casual donor is a donor who does not regularly engage in a systematic plasmapheresis program, but who does so only occasionally, usually at times separated over many months. Casual donors would be effectively excluded from engaging in plasmapheresis under the County ordinances because they would need County donor identification cards, which would be burdensome to obtain and would be valid for only six months. Additionally, those donors who participate elsewhere in a plasmapheresis program on a regular basis, but who find themselves in Hillsborough County only for a short period of time, would be effectively excluded from continuing to participate as plasma donors while in the County of Hillsborough (TR 54-55).

While it is true that the County has a legitimate interest in protecting the health and safety of its citizens, any such protection provided by the subject ordinances is illusory. None of the features of the County regulations accomplishes a purpose that the federal regulatory system does not accomplish, and none provides protection to the people of Hillsborough County not afforded by the comprehensive federal regulations.

Because enforcement of the County ordinances would, in the above respects, stand as an obstacle to the accomplishment and execution of the purposes of Congress in establishing a national blood policy, the ordinances are pre-empted by the federal regulatory system.

CONCLUSION

The Eleventh Circuit properly determined, based upon criteria set forth by this Court, that the subject Ordinances are pre-empted by federal regulation. For the reasons stated herein, the judgment below should be affirmed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

All parties required to be served have been served by depositing on this 29th day of March, 1985 three printed copies of this document in a U.S. Post Office, with first class postage prepaid, addressed to counsel of record at his or her post office address as follows:

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